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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/889,379	07/16/2001	Hiroshi Sugiyama	56212 (71526)	2742

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EXAMINER

TUNG, JOYCE

ART UNIT	PAPER NUMBER
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1637

DATE MAILED: 01/15/2003

18

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.
09/889,379

Applicant(s)

Sugiyama et al.

Examiner

Joyce Tung

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Nov 1, 2002
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-19 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5, 8, 10, 11, 15, 17, and 19 is/are rejected.
- 7) ☒ Claim(s) 6, 7, 9, 12-14, 16, and 18 is/are objected to.
- 8) ☒ Claims 1-19 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.

2. ☐ Certified copies of the priority documents have been received in Application No. _____

3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
- a) ☐ The translation of the foreign language provisional application has been received.

- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)

4) ☐ Interview Summary (PTO-413) Paper No(s). _____

2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

5) ☐ Notice of Informal Patent Application (PTO-152)

3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 17

6) ☐ Other:

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DETAILED ACTION

Election/Restriction

1. Applicant's election without traverse of Group I, claims 1-19 in Paper No. 16 is acknowledged. Since there is no argument regarding the restriction requirement, the election is considered to be without traverse.

Claim Objections

2. Claims 6-7, 9, 12, 13-14, 16 and 18 are objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim from claims 1-5 or 1-6, 1-8 or 1-11 or 1-13 or 7-12 or 2-15 or 1-17. See MPEP § 608.01(n). Accordingly, the claims 6-7, 9, 12, 13-14, 16 and 18 have not been further treated on the merits.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
4. Claims 1-5, 8, 10-11, 15,17, and 19 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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- a. Claims 1-5, 8, 10-11, 15 and 17 are vague and indefinite because there are no active steps in the method to describe how to detect or identify an action of a chemical species A to a substance containing DNA or RNA.
- b. Claims 2-5 and 19 are vague and indefinite because of the language "assaying a state of the substance containing DNA or RNA" in claims 2 and 19. It is unclear what is the definition of "a state". Clarification is required.
- c. Claims 1-5, 8, 10-11, 15 and 17 are vague and indefinite because it is unclear whether or not the phrase "a chemical species A" in claims 1 and 2 is the same as the chemical structure A in the formula (I). Clarification is required.
- d. Claims 1-5, 8, 10-11, 15 and 17 are vague and indefinite because the phrase "recognize" in claims 1 and 3-4 is unclear whether or not the phrase means that the chemical species has physical contact with a base sequence of DNA. Clarification is required.
- e. Claim 3 is vague and indefinite because the claim language "recognize a difference of the base sequence of DNA or RNA of the substance containing DNA or RNA and the substance containing DNA or RNA which is introduced into each well is the same substances" is unclear what it is meant.
- f. Claims 1-5 and 19 are vague and indefinite because it is unclear how the language "non-natural bases" is defined. Does it mean that the bases are synthetic bases? Clarification is required.

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g. Claims 17 is vague and indefinite because of the language "detecting survival or death of the substance is coloring or the substance". It is unclear what is meant by "substance".

Clarification is required.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 1-2, 4-5, 8, 10, and 15 are rejected under 35 U.S.C. 102(b) as being anticipated by Lee et al. (5,273,991).

Lee et al. disclose Imidazole-substituted oligopeptide derivatives which are conjugated to DNA alkylating agents. The compounds are useful as antitumor agents (See column 2, lines 58-61). Two, three or four imidazole groups are joined by carboxamido linkages (See column 4, lines 56-58), The compounds are capable of binding to the minor groove of double stranded DNA (See column 8, lines 63-67). The compound is used to inhibit the growth of various cancers (See column 9, lines 30-41). The invention is directed to a method of treatment of cancers (See column 9, lines 40-44). This teaching is inherent that there is the method for detecting or identify the action of the compounds. The cells are tumor cells (See column 23, lines 1-6). The

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compounds aliquots were added to the plate wells (See column 23, lines 7-12). Thus the teachings of Lee et al. anticipate the limitations of claims 1-2, 4-5, 8, 10, and 15.

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

8. Claim 17 is rejected under 35 U.S.C. 103(a) as being unpatentable over Lee et al. (5,273,991).

The teachings of Lee et al. are set forth in section 6 above and Lee et al. do not disclose a kit containing the compound for performing the method. However, it would have been prima facie obvious to construct a kit with the reagents needed for perform a method because it was

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well known the art at the time of instant invention to construct the kit for the convenience of performing the method.

9. Any inquiries concerning this communication or earlier communications from the examiner should be directed to Joyce Tung whose telephone number is (703) 305-7112. The examiner can normally be reached on Monday-Friday from 8:00 AM-4:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached at (703) 308-1119 on Monday-Friday from 10:00 AM-6:00 PM.

Any inquiries of a general nature or relating to the status of this application should be directed to the Chemical/Matrix receptionist whose telephone number is (703) 308-0196.

10. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Art Unit 1637 via the PTO Fax Center located in Crystal Mall 1 using (703) 305-3014 or 308-4242. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989).

Joyce Tung

Joyce Tung
January 10, 2003

Jeffrey Siew
JEFFREY SIEW
PRIMARY EXAMINER
1/13/03